

HOUSE FINANCE COMMITTEE

SENATE FINANCE COMMITTEE

**BIOSCIENCE DISCOVERY EVALUATION GRANT
PROGRAM UPDATE**

as of

June 30, 2013

**Legislative Report to House and Senate Finance Committees
per CRS 24-48.5-108
Bioscience Discovery Evaluation Grant Program
By the Colorado Office of Economic Development and International Trade**

The Bioscience Discovery Evaluation Grant Program (BDEGP) and Cash Fund was first created in statute in 2006; the program will terminate in January 2015; the mission for supporting the development of novel technologies and commercializing those in Colorado will be continued under the new Advanced Industry Accelerator Program. In its seventh year, fiscal year 2012-13, the program continued to offer three targeted grant programs to support the Colorado bioscience industry. The BDEGP has been praised for its effectiveness in leveraging a limited state investment to move promising commercial technologies to market and for supporting the development of the biotechnology industry in Colorado.

Commercialization Infrastructure grants support joint efforts of industry and academia to create resources that are essential to industry growth. BDEG Commercialization Infrastructure funds have funded 4 organizations over a number of years. Two new organizations, The Colorado Institute for Drug, Device and Diagnostic Development and The Colorado Center for Drug Discovery were started to address needs identified by the industry. The BioFrontiers Institute at the University of Colorado Boulder, and the School of Pharmacy at the University of Colorado Anschutz Medical Campus have developed Core Facilities that offer new critical technologies to advance drug discoveries. Grantees identify and manage technologies, and support collaboration to bring necessary expertise together to advance novel Colorado biotechnologies to commercialization.

The Colorado Center for Drug Discovery (C2D2) based at Colorado State University is a resource to faculty at Colorado research universities, bringing biology and chemistry faculty together to use chemical libraries, computational resources, bioinformatics, cheminformatics, database support, virtual high throughput screening, and Computer Aided Drug Design to pharmacologically validate drug candidates with patent-protected chemical matter and innovative therapeutics for unmet medical needs. C2D2 supports several inter-institutional projects with funding and resources. C2D2 offers compounds to investigators through its screening library and medicinal chemistry services that are critical in the drug discovery process.

The Colorado Institute for Drug, Device and Diagnostic Development (CID4) is managing life science discoveries from Colorado research institutions and Colorado start-ups and early-stage businesses with the goal of creating bioscience jobs in Colorado. Grant Funds support operations of the CID4 and the development and management of life-science discoveries adopted as Projects of the CID4. The CID4 has 7 early stage companies under its guidance supporting their operational development and attracting additional investment to meet their needs.

The BioFrontiers Institute is a state-of-the art research and education facility that links the basic sciences, engineering, clinical practice, and industry at the University of Colorado's Boulder campus to support breakthrough developments in areas such as engineering human tissues, RNA enzyme and aptamer based pharmaceutical, biorefining, and genetics. Grant funds support

equipment, resources and personnel costs to develop the core facilities of the institute. With grant support, the institute has developed one of the largest repositories of shRNAs in the world at the Functional Genomics Facility. Colorado companies partner with the institute to improve their products. Ventria, a Fort Collins based pharma-biologics company has used mass spectrometry services to detect oxidation in recombinant protein samples manufactures for human therapeutics. OPX Biotechnologies based in Boulder utilizes mass spectrometry to detect levels of intracellular metabolites in biofuel molecule samples. Longmont-based Avery Brewing Co. has partnered with the Next-Generation DNA Sequencing Facility to develop an early-detection test for yeast cross-contamination to reduce waste and inefficiencies in their production process.

The University of Colorado, Skagg's School of Pharmacy at Anschutz developed an HTS/HCS (high throughput/content screening) Core Facility for drug discovery. This resources has been utilized by more than 100 researchers and companies advancing the science and helping to secure intellectual property.

Proof of Concept (POC) grants substantiate research at Colorado research institutions with commercial applications. Since the first grants were made in mid-to-late 2007 through fiscal year 2013 the program has awarded 163 grants to researchers at Colorado research institutions to bring their cutting-edge technologies closer to market. These grants are usually matched by funds from the technology transfer offices to allow the investigators to reach commercialization milestones. The table below shows how these have flourished by attracting additional capital resources, firming up intellectual property rights, and either being licensed out to companies or having companies formed around the commercial potential of the technology.

Early-Stage Company (ESC) grants provide needed funding to companies commercializing technologies from Colorado research institutions by backing research, testing, and business development activities that will prepare them for additional third-party financing. Under the Early-Stage Company program 53 grants have helped companies further advance biotechnologies coming out of Colorado research institutions. BDEG grants allow early-stage businesses to complete studies, secure intellectual property, and develop their business models to bring their products to market.

The program's statute requires an allocation of at least 30% of the funds to Proof of Concept grants, 30% of the funds to Early-Stage Company grants, and up to 40% of the funds to Commercialization Infrastructure. The table below summarizes all grants awarded by June 30th 2013. The metrics are grouped by active and closed. As bioscience technologies generally have a long development time-line we often see few commercialization metrics in the near-term. We track developments following the close of these grants to better understand the impact. The Company SBIR/STTR grants were offered per statutes in fiscal year 2008; these required that the applicant have an active federal Small Business Innovation Research or a Small Business Technology Transfer grant and two-times the BDEG award sought in order to apply. The statutes were amended to offer the ESCR program in fiscal year 2009.

Status	Program	Number	\$ Awarded	\$ Spent to date	\$ Matched to date	Jobs Created	Companies Created	Follow-on Capital	Intellectual Property Advancements	Licenses Issued
Closed Grants	Proof of Concept	117	\$ 7,116,185	\$ 6,874,852	\$ 7,380,456	124.4	36	\$ 291,409,206	50	32
	Company Grants									
	SBIR/STTR	12	\$ 755,073	\$ 755,073	\$ 2,128,497	19.0		\$ 19,509,849	6	0
	Early Stage Company	30	\$ 4,367,100	\$ 4,268,255	\$ 6,540,637	93.0	2	\$ 63,859,504	19	2
Active Grants	Infrastructure ¹	4	\$ 10,242,090	\$ 8,170,991	\$ 20,875,767	111.5	5	\$ 35,319,740	2	2
	Proof of Concept	46	\$ 2,864,948	\$ 573,618	\$ 484,892	12.7	2	\$ 1,327,000	9	2
	Early Stage Company	11	\$ 2,070,105	\$ 1,176,112	\$ 1,494,948	20.7		\$ 7,199,000	4	1
	TOTALS	220	\$27,415,501	\$21,818,901	\$ 38,905,197	381.2	45	\$ 418,624,299	90	39

The State leverages this investment in the industry by requiring a one-to-one match for both Proof of Concept and Early-Stage Company grants. The economic benefit is realized near-term in the strengthening of our research institutions, the jobs required to fulfill the grant work, and the products and services purchased to complete grant work. Longer-run payouts come in the form of additional capital investment into the technologies and companies, the creation of new companies, and growing businesses adding high quality jobs. Approximately \$27 million from the BDEGP Cash Fund has been granted and garnered more than \$38 million in matching funds. Of 220 grants awarded under the program by the end of fiscal year 2013, 159 have completed work while the others are in process. The chart above shows returns realized during the grant term, and those that continue to accrue as the technologies become closer to and actually enter the market-place. To date, the program successes include the creation of 45 new Colorado companies and the direct creation of approximately 381 jobs. Additionally, these funds have helped the technologies acquire an additional \$418 million dollars in grants and investments to further commercialize these bioscience technologies.

The BDEG Program has provided critical gap funding to many technologies in early development. Sometimes the grant projects reveal that a technology is ineffective, or has hurdles to over-come. Many evolve into viable products and services. Here are a few stories...

A Proof of Concept grant funded investigators at the University of Colorado in developing redox-initiated radical chain polymerization for the detection and amplification of biological recognition events. The work resulted in intellectual property claims that were later licensed out to InDevR, a Boulder-based business formed by the scientists. InDevR secured funding from the National Institutes of Health and was subsequently awarded a BDEG Early-Stage Company Grant to aid with commercialization. The company is now in the revenue stage offering commercial assays and instruments for research and development. InDevR has created 25 jobs and acquired more than \$10 million in follow-on capital.

In 2009, Colorado State University scientists Andrew Ray and Susan Bailey were awarded a Proof of Concept Grant to develop fluorescently-labeled probes for identifying specific recurrent point mutations in cancer cells. By the close of the grant, a patent had been filed and KromaTiD was formed in Fort Collins. KromaTiD later sought funding from the ESC Program for

development of their novel chromosomal inversion detection technology, but were directed by the review committee to first focus their business offering before progressing further with scientific work. The business plan helped the company target the research and development market. KromaTiD then gained the guidance of the Colorado Institute for Drug, Device and Diagnostic Development – a BDEG funded commercialization infrastructure asset – and is earning revenues on their assays for detecting chromosomal rearrangements. In 2013 KromaTiD was awarded an ESC grant to develop a new medical R&D product.

Boulder based Mosaic Biosciences received an Early-Stage Company grant in spring of 2011 to advance their novel tissue regeneration technology licensed from the University of Colorado. Grant funds supported pre-clinical efficacy and toxicity studies, manufacturing scale-up, intellectual property protection and solicitation of investors. The work accomplished with BDEG funding resulted in substantial improvements to the product material, and positioned the company to close on their first round of financing for over \$ 1million.

Thirty-four projects were approved for funding in fiscal year 2013. Total grant funds awarded to these projects exceed \$4 million dollars. The table summarizes these awards.

Program	Grantee	Associated Research Institution	Primary Investigator	Subject	Award \$
ESC	Aurora Oncology, Inc.	CU		DT-EGF fusion protein for treatment of bladder cancer	146,880
ESC	Barofold, Inc	CU		PreEMT high pressure refolding of biosimilar insulin glargine	123,225
ESC	Double Helix, LLC	CU		Widefield 3D superresolution microscopy instrumentation for biomedical sciences	50,000
ESC	KromaTID, Inc.	CSU		Product development and launch of GSSH assay kits and reagents for disease research and diagnostic testing	100,000
ESC	Siva Therapeutics Inc	CSM		Smart polymers for improved photothermal cancer therapy	250,000
ESC	SixOne Solutions	CU		Optimized Eya2 inhibitors for treating breast cancer	50,000
ESC	SmartMove	CU		Fighting "sitting disease" study	200,000
ESC	Tissue Fusion	CU		Developing laser-based medical devices to fuse biological tissue together as an alternative to sutures or staples, starting with an instrument for nasal procedures	75,000
ESC	Xalud Therapeutics, Inc.	CU		Development of a first-in-class multiple sclerosis treatment	222,000
INFR	Colorado Institute for Drug, Device and Diagnostic Development			Colorado Institute for Drug, Device and Diagnostic Development	773,231
INFR	Colorado State University			Colorado Center for Drug Development	500,326
INFR	Regents of the University of Colorado (CIMB)			BioFrontiers Institute	636,778
POC	Colorado School of Mines TTO	CSM	Krebs	Biopolymer hydrogels for the controlled, localized delivery of therapeutic antibodies	42,070
POC	Colorado School of Mines TTO	CSM	Boyes	Polymer modified nanoparticles as contrast agents for the non-invasive measurement of pH in vitro	87,173
POC	Colorado State University Research Foundation TTO	CSU	Orton	Catheter-delivered artificial heart valve device	66,432
POC	Colorado State University Research Foundation TTO	CSU	Williams	Largazole analogs, class 1 isoform selective HDACi's: scale-up and efficacy studies in autoimmunity and cancer	44,387
POC	Colorado State University Research Foundation TTO	CSU	Chen	Sustainable and high-performance bioplastics from renewable plant biomass	40,065
POC	Colorado State University Research Foundation TTO	CSU	Miknis	New methods to prepare peracids	17,592
POC	Colorado State University Research Foundation TTO	CSU	Lear	Prototype optical chip for proteomics	20,135
POC	Colorado State University Research Foundation TTO	CSU	Dow	Novel non-adjuvant drugs for enhancing vaccine efficacy	59,940
POC	National Jewish Health TTO	NJH	Lucas	Cdk6 as a breast cancer biomarker - preclinical exploratory and validation phase	22,000
POC	National Jewish Health TTO	NJH	Gelfand	Targeting PIM1 kinase in the treatment of allergic diseases	21,997
POC	National Jewish Health TTO	NJH	Chu_Zhang	SPLUNC1, a novel therapy of infection and inflammation	22,000
POC	National Jewish Health TTO	NJH	Pacheco_Nagabhushanam	Development and validation of diagnostic assays for metal and bone cement allergy in joint implant failure	22,470
POC	National Jewish Health TTO	NJH	Strong	Development of a novel molecular diagnostic for nontuberculous mycobacterial infections	22,000
POC	University of Colorado TTO	CU	Chen	Three-dimensional percutaneous coronary intervention (PCI) planner system	88,553
POC	University of Colorado TTO	CU	Leinwand	Fatty acid induced cardioprotection and treatment of pathological cardiac hypertrophy	69,986
POC	University of Colorado TTO	CU	Yin	Therapeutics for treating chronic pain and improving the clinical utility of opioids	70,000
POC	University of Colorado TTO	CU	Doebele_Garcia	Methods for diagnosis and treatment of cancer	66,335
POC	University of Colorado TTO	CU	Graham	Development of axl-Fc for oncology applications	66,414
POC	University of Colorado TTO	CU	Reid	Small molecule therapies for prevention of cardiomyocyte hypertrophy	88,553
POC	University of Colorado TTO	CU	Shandas	Shape memory polymer integrated surgical mesh for hernia repair application	59,104
POC	University of Colorado TTO	CU	Tan	Chemical glycoengineering of insulin for type 2 diabetes treatment	70,000
POC	University of Northern CO	UNC	Patrick Burns	Initial design of a clarifying device for sperm viability for cattle reproduction	50,000